

### REMARKS

This Preliminary Amendment accompanies a Request for Continued Examination.

Applicants have amended claim 1. Support for the amendment can be found, *e.g.*, in the originally-filed specification at ¶ [0076]. No new matter has been added.

Claims 1-6 and 16-17 are presented for further examination.

#### Rejections Under 35 U.S.C. § 112

The Office action rejected claims 1-6 and 16-17 under 35 U.S.C. § 112, ¶ 1 as allegedly indefinite. In particular, the Office action asserted that the hydrogen peroxide eluting amount of 5 ppm or less, and/or the eluate containing certain UV absorbance would depend on the composition of the eluate or on the amount of liquid used in the extraction. *See* Office action at p. 2.

Claim 1 recites that the absorbance of the resultant solution is measured at a wavelength of 508 nm. Accordingly, the hydrogen peroxide eluting amount does not depend on the composition of the eluate. Claim 1 also recites that a solution mixture is added to an eluate (2.6 ml) obtained by an elution test regulated in the Approval Standard for Dialysis-type Artificial Kidney Apparatus. In this regard, the method regulated in the Approval Standard describes that pure water (100 ml) is added to the hollow fiber membranes (1 g) and elution is made from the wet hollow fiber membranes at 70°C for one hour. *See* Application at ¶ [0076].

The Office action also alleges that there is no basis for the 5 ppm amount of hydrogen peroxide, *i.e.*, whether the basis is with respect to the mass of the membrane or the mass of the eluate. *See* Office action at pp. 2-3. For purposes of clarity, Applicants have amended claim 1 to recite that the 5 ppm amount is with respect to the mass of the hollow fiber membrane bundle.

Applicants therefore respectfully request that the rejection be withdrawn.

#### Rejections Under 35 U.S.C. §§ 102/103

The Office action rejected claims 1-6 and 16-17 are anticipated by or, in the alternative, obvious from, U.S. Patent No. 6,103,117 (Shimagaki). The Office action argues that although

the claimed hydrogen peroxide concentration is not disclosed in the Shimagaki reference, it is inherent or obvious. Applicants respectfully traverse the rejection.

“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP § 2112 (*quoting Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)). Nowhere in the Shimagaki patent is there disclosed any measures that would achieve the claimed hydrogen peroxide concentration. At the very least, the Office action has failed to point to facts or provide technical reasoning as to why the claimed hydrogen peroxide concentration “necessarily flows” from features disclosed in the Shimagaki patent.

Claim 1 is also not rendered obvious by the cited art. The Office action admits that the Shimigaki patent fails to disclose at least two claim features, but makes no argument why the claimed subject matter is rendered obvious by the cited art. *See* Office action at p. 3. The Office action therefore fails to make a *prima facie* case of obviousness because “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *See* MPEP §§ 2142-2143.

The Office action also fails to account for secondary considerations of non-obviousness disclosed in the specification. For example, one unexpectedly advantageous or superior property of the claimed invention is its improved storage stability. *See* Application at ¶ [0010]. That advantage is achieved by inhibiting the generation of hydrogen peroxide. The Shimagaki patent does not disclose either the object of improving storage stability or the claimed concentration of hydrogen peroxide. *See* Office action at p. 3 (admitting that the Shimagaki patent does not disclose the claimed hydrogen peroxide concentration). Therefore, the Shimagaki patent does not disclose or suggest any means for inhibiting the generation of hydrogen peroxide. Specifically, the hydrogen peroxide contained in poly(vinylpyrrolidone) as a material (*see* Application at ¶ [0019]) is also generated in the step of dissolving the material (*see* Application at ¶ [0032]) and in the step of producing the hollow fiber membranes as well as in the step of

sterilization after being fabricated into a module (*see* Application at ¶ [0024]). Although every consideration as mentioned above should be made in each step to achieve the claimed hydrogen concentration of 5 ppm, the Shimagaki patent does not disclose that a material with a reduced amount of hydrogen peroxide should be used, that the influence of heating and oxygen during the dissolution step and the drying step should be removed, or that the step of sterilization (crosslinking) in consideration of the influence of moisture and oxygen should be applied. Therefore, the Shimigaki patent does not render obvious claim 1.

Applicants respectfully submit that claim 1 is patentable over the cited art. Claims 2-6 and 16-17 recite additional features and are independently patentable.

#### Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The RCE fee of \$810.00 and extension of time fee of \$130.00 are being paid over the EFS by way of deposit account authorization. Please apply any other charges or credits to deposit account 06-1050.

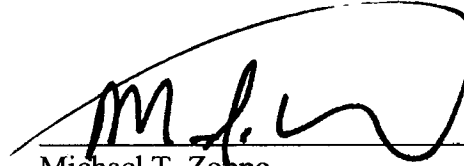
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Respectfully submitted,

Date: \_\_\_\_\_

8.17.09

A handwritten signature in black ink, appearing to read 'M. Zoppo', written over a horizontal line.

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